



Study Managers/Business Management Meetings Sept /Oct 2009.

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER IN ATRAZINE LITIGATION

GRNVL0000066214

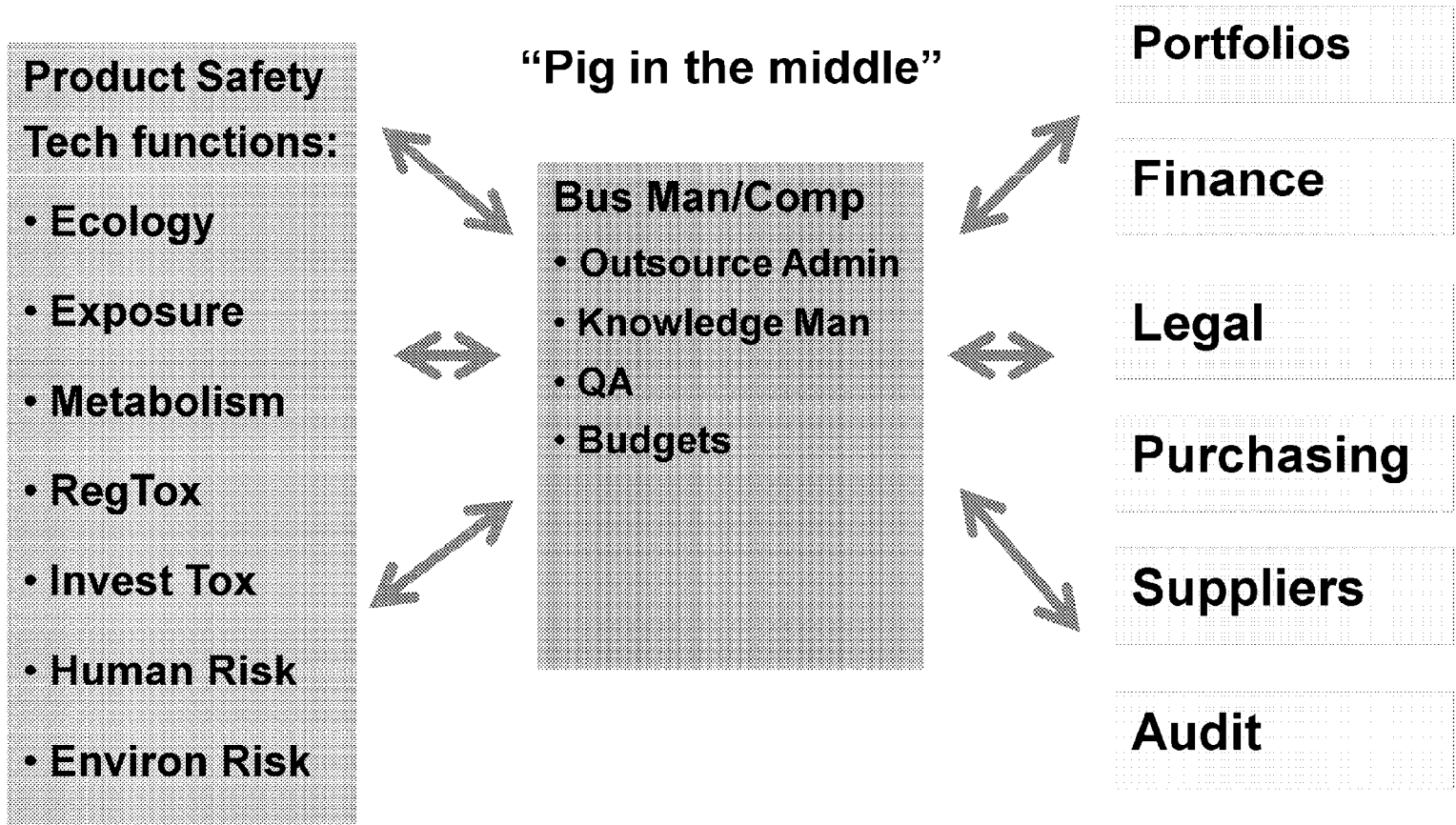
Background

- Feedback from study managers meetings
- Follow-up from previous liaison meetings
- New starters
- All processes evolving inc.
 - arrival of Smartchoice
 - Legal
 - Finance
- Changes in BM
- This is a presentation + discussion !!!!!

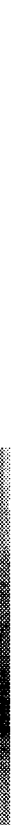
Agenda

- **Business management and compliance - Where we sit ?**
- **Organisation**
- **Knowledge Management**
- **Mandatory processes – legal / finance**
- **Outsourcing process/ Impact SmartChoice**
- **Budgets**
- **Report Templates**
- **Function questions**

Business management and compliance - Where we sit ?



Business management and compliance - Who are we ?



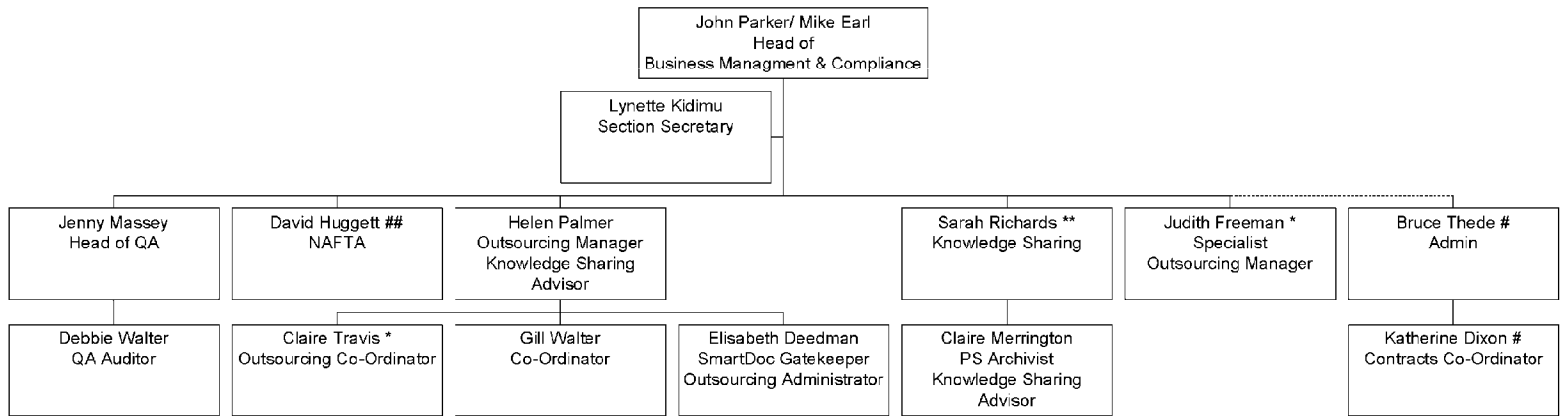
+



We really don't mean to be..... ..We want to be

#14146

Business Management & Compliance



Based in the US – Greensboro
 * Part Time
 ** Maternity Leave
 ## International Assignment (SBI until March 2010)

617th March 2009

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER IN ATRAZINE LITIGATION

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Knowledge Sharing : Archiving, Teamspace (Plus) MOSS

Study Managers Mtg

CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER IN ATRAZINE LITIGATION

GRNVL0000066220

What is Knowledge Sharing currently involved with.....^{#14148}

- Archiving
- Teamspace/ Teamspace Plus
- MOSS
- Smartdoc
- Smartstore
- Smartchoice
- Report Templates
- System mapping

Archiving

- **Opening Times:**

➤ **Every Tuesday and Thursday between 10am & 12noon**

If they are to be closed on those dates/times, an email will be sent out.

- **Urgent ad hoc retrievals contact Claire Merrington (Archivist) or Susan Richardson (deputy Archivist)**

Where can I find more information?

- **Ask The Archivist – Claire Merrington – ext. 4417 or email:
the.archivist@syngenta.com / Archivist The GBJH**
- **Look on the Archiving Teamspace
<http://ts1.pro.intra/sites/CPDPSArchive/default.aspx>**

Where is my data?

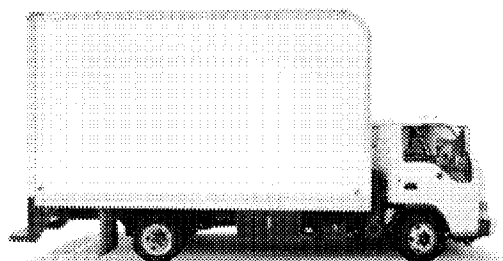
In deepstore

Tox data from CTL archives
Yalding data and Lab notebooks
Some JH data



Being transferred to Deepstore

JH Data (6+ years in JH archive)
All E-fate, D-Exposure data from
1995- 2002



Still in JH archive

All data from closed JH facilities that
have been held in archives for less
than 6 years

Data retrieval

Q. How do I get my data?

- **A. Complete a Loan request form**
 - Deepstore request form
 - Or Jealotts Hill request form

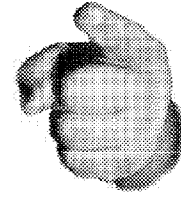
Q. How long can I keep the data for?

- **A. JH data can be loaned max 3 months**
- **A. Deepstore for a max of 4 weeks.**
 - Lack of space in archive
 - Archives can be inspected at anytime – unprofessional
 - We are paying to hold boxes in Deepstore not JH
- **If you do not come to the archive to look at your retrieved data it will be returned to Deepstore. All transfer costs will be charged to YOUR section**

Archiving Strategy – 2010 and beyond

- Archiving cost will rise significantly with Outsourcing strategy
- Currently spend ~\$1.5m on external archiving
- Bulk at Harlan (\$1m)– ex-Stein, ex-Rosental archives
- Deepstore – low cost archiving solution
- Strategy to address archiving – addressing:
 - QA issues
 - MHRA requirements
 - limit storage to J Hill archive and deepstore

Internal Teamspaces:




House-Keeping:

- This is **YOUR** responsibility to ensure the teamspaces are kept tidy.
- Only live documents should be held on a Teamspace.
- All other docs can be put into Smartdoc, Smartstore (or deleted)
- Remember to tidy the Version history
- Keeping your teamspace clutter-free means it works faster

General Information:

- A Teamspace user guide can be found on the KnowHow website or on the Knowledge Sharing Teamspace

[mySyngenta home](#) [Syngenta director](#) [Search](#) [People finder](#) [Location finder](#) [Feedback](#) [Help](#) **syngenta**

Search... 

☒ All of Syngenta ☐ People finder

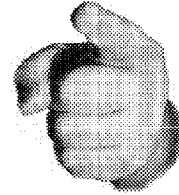
Security:

- Use teamspaces to share more sensitive documents
- It is against company policy to share sensitive documents via email and it is also not secure.
- Remember email is not secure.

Teamspace Plus (external teamspace)

House-Keeping:

- As with the internal teamspace, this is **YOUR** responsibility to ensure its tidy
- TS+ site/ Announcements - there is a document detailing the house-keeping responsibilities of the study managers.

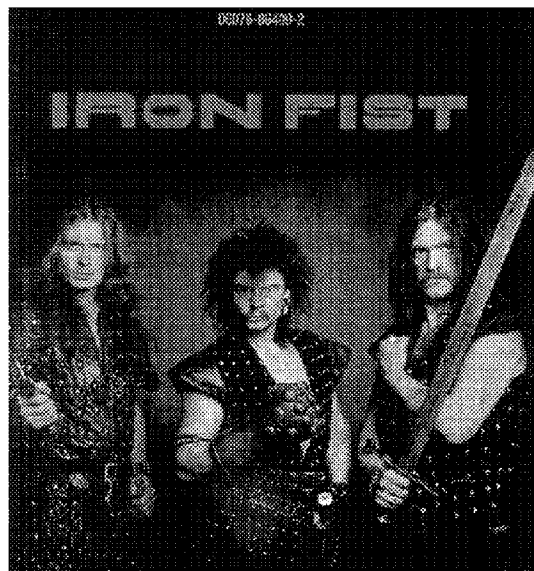


Security:

- You should be using TS+ sites to share sensitive documents e.g. commercial information, study data, etc with any external colleagues, as it is **against company policy** to share sensitive documents via email.
- Using the TS will help reduce the risk of documents going missing or being intercepted if sent via the postal system or via email.
- TS+ sites are a secure way of sharing documents, and for some sites digital IDs are required as they contain very sensitive documents

**“We are protecting you
(and Syngenta)”**

- **Legal**
 - **Secrecy agreements**
 - prior to any technical discussion
 - **Terms and Conditions**
 - before any quotes are requested
- **Finance**
 - **Quotations/contract detailing costs**
 - **Purchase Order (PO)**
 - official trigger for CRO to start
 - **Quote/contract Amendments**
 - if the scope of work changes
 - **Invoices – must have had a quote before an invoice!!**



ALL ABOVE ARE AUDITABLE !!!!!!!!!!!!!!!!!!!!!!!

- **Technical due diligence (inc QA checks) / Animal Welfare (if applicable)**

Process – Demand and Supplier Selection

- **Outsourcing works with functions/Portfolios to define demand**
 - **Type of studies and number required**
 - **SMARTChoice**
- **Identify new suppliers - basic selection criteria:**
 - **Suppliers technical capability**
 - **Quality issues/ GLP/ Regulatory acceptance**
 - **Compliance with Syngenta animal welfare policy**
 - **Global strategy for inspections**
 - **Location**
 - **Value**
 - **Financial audit**
 - **Ease of use !!!!!!!!!!!!!!!**
- **Agree annual supplier base – functional supplier matrices**
 - **Preferred and approved suppliers**

Process – Negotiation

- **Pricing and Service level agreements**
 - **Baseline pricing**
 - **Benchmarking**
 - **Competitive bidding**
 - **Volume discounts**

Process – Research Agreements

Exactly the same process as described except:

- **Agreements negotiated by Mike Lant**
- **Legal counsel sign agreements**

- **2 types of agreement**
 - **Collaboration. These must be agreed through Mike Lant**
 - **Potential IP issues**
 - **Potential publication issues**
 - **Tend to be long term**
 - **Should be on Peter Campbell's Science Credibility list**
 - **'Fee for service'**
 - **No IP or publication issues**
 - **Short term**
 - **Can be set up by outsourcing**

Process – Work Placement

- **Function identify required work**
 - **SMARTChoice**
 - Task set to Active by Project Manager**
 - Task Contact Completed – by function**
 - Task location set – by function**
- **Quotation requested from supplier (1 task per quote) by function via Sharepoint Teamspace plus if available.**
- **Quotation checked by work requestor and passed to Outsourcing (email to BM to proceed – we will chase!!!!)**
- **Quotation signed by Syngenta Ltd signatory, Helen Palmer, John Parker or John Doe or Mike Bushell and returned to CRO**
- **Quotation stored on Outsourcing TeamSpace**
- **Quotation used to raise an order in ORBITOOL**
 - **Excludes the Harlan group (SLA)**

Process – Quotation details required

Quotation:

Headed paper

Quotation reference

Technical specification (summary)

SMARTChoice Activity ID and /or SYPOS task ID

Study manager/Work requestor name

Deadline

Start and finish dates

Total cost (discount detail)

**Invoice schedule (stating costs and month/year
expected to be sent)**

Reference to Syngenta Ltd T&Cs

ALL ABOVE COMPLETE THEN:

Sponsor's signature – Syngenta Signatory

Process – Budget Approval and PO's

Post Quotation accepted

- Order in Orbitool is approved by cost centre manager
- Purchase order number faxed to supplier to confirm work placement – THIS IS OFFICIAL TRIGGER FOR CRO TO START AS PER T&C's
- TeamSpace and TRAX updated
- SMARTChoice external resources revised to equal at least contracted costs
- We can obtain “emergency PO's” - this should be exception not the rule!!!!

Process – PO's and Invoices

- **Invoices received via Teamspace plus as a .pdf, by Business Management or otherwise by Email**
 - **First payments made (generally on contract signature)**
 - **Further invoice payments made after confirmation of milestone by study manager**
- **Payment made subject to the T&Cs, normally within 30 days of the month following invoice date.**
- **Issues with invoice payment – being addressed with Huddersfield**
- **We do not own the process**
- **If you are contacted by CRO regarding invoice payments refer to Business Management**
- **Contract amendments important to increase PO and ensure payment**

Process – Invoices details required

Invoice:

Headed paper

SYNGENTA Ltd address

SmartChoice Activity ID and/or SYPOS ID

CRO invoice number

Original quotation reference

Purchase order number

Total value

**Invoice milestone i.e. Scheduled payment –
final ?**

Pitfalls to Avoid

Please DO NOT....

... Initiate work prior to:

Technical competence determined

Animal welfare inspection

T&Cs being signed

Cost centre manager's approval / Purchase order being issued

... sign T&Cs unless you are an authorised signatory for Syngenta Ltd

... sign quotations unless you are an authorised signatory for Syngenta Ltd

... Send quotations or invoices to Business Management lacking necessary information

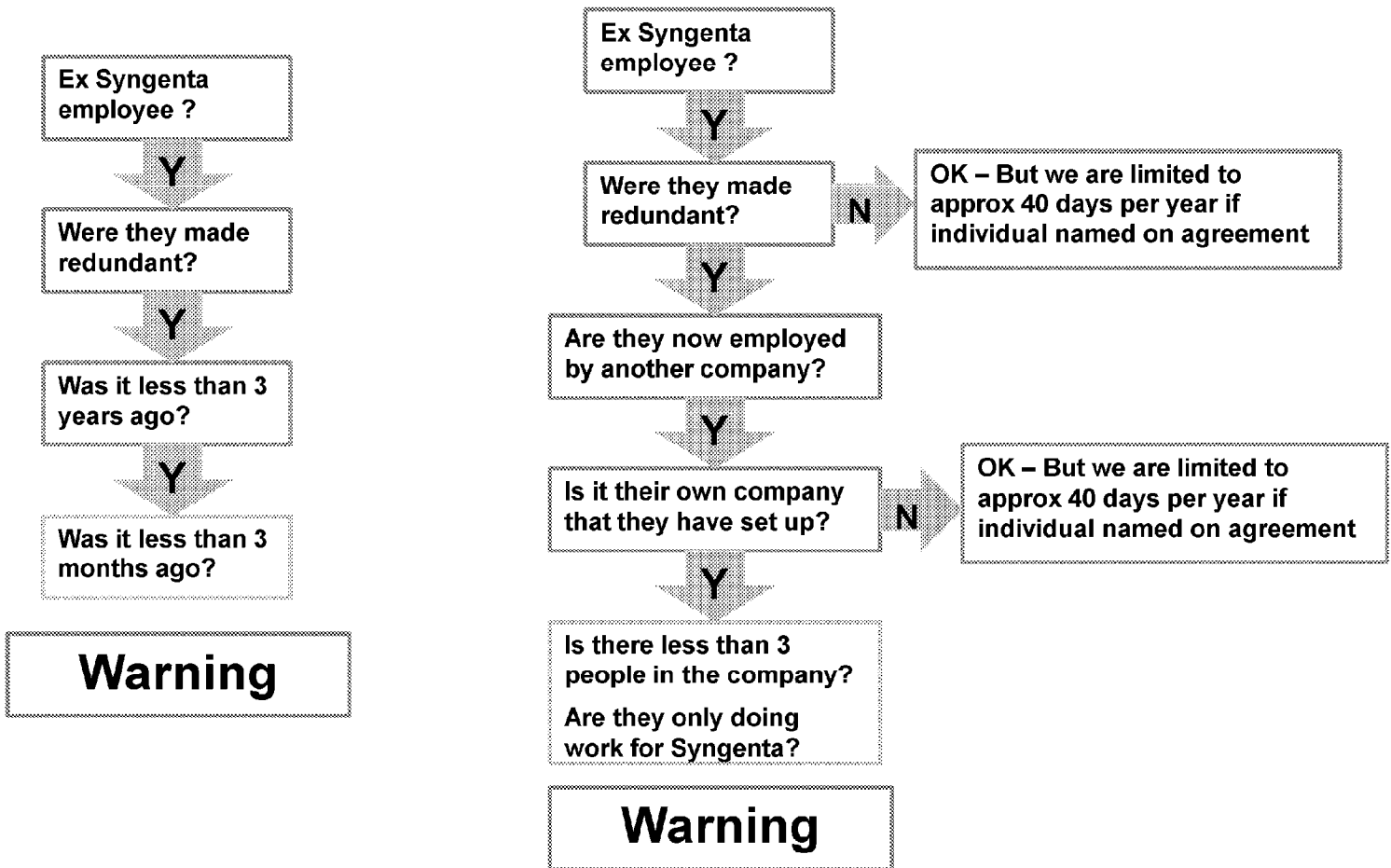
... task not approved by business or set correctly in SMARTChoice

... receive invoices for more than one purchase order number

Consultancy/ Service agreements - Rules of re-engagement

- **Aim – To minimize the risk to Syngenta.**
- **There are 2 sets of rules**
 - **Inland revenue rules**
 - **Can claim back the tax on redundancy payment, NI etc**
 - **HR rules**
 - **Ex Syngenta employee may claim to be unfairly made redundant**
 - **Non Syngenta person may claim for pension contribution etc.**

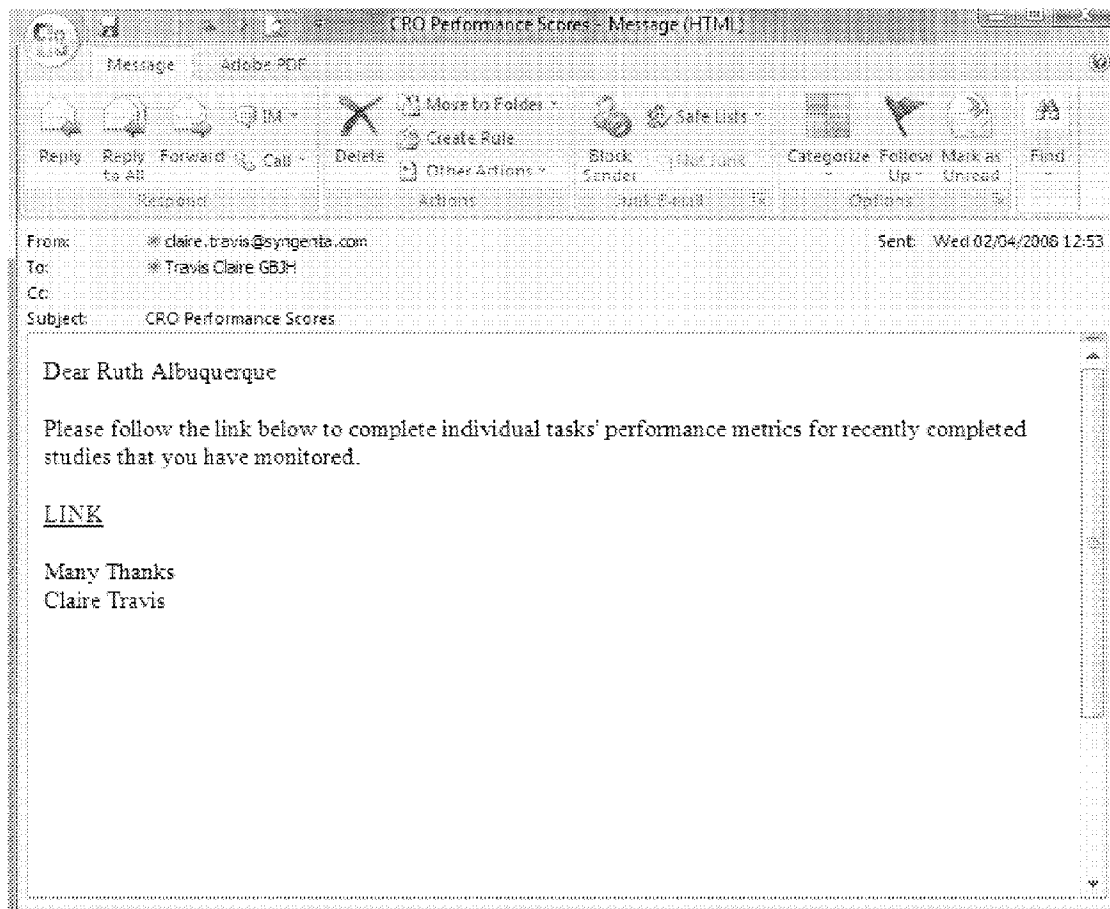
Consultancy/ Service agreements - Rules of re-engagement



Process – Supplier Performance

- **Specific technical issues**
 - **Study manager to study director**
- **Significant technical issues**
 - **Study manager to study director**
 - **Project lead and Outsourcing informed**
- **Outsourcing will begin to collect study specific performance data following task completion**
 - **Quality, timeliness, communication**
 - **1 to 5 score via web application**
- **Supplier review**
 - **Function and Outsourcing input**

Once a month if appropriate an automated email is sent containing a link to a web interface



Contracts missing KPIs for user ctravis

There are no contracts without KPIs for this user.

If you require assistance or believe that you have received this message in error please contact Clare Travis claire.travis@syngenta.com

If you save the link it will update as it is a live link to the TRAX database.

So if you have completed the responses it will let you know there is nothing outstanding.

Otherwise the link will give you a list of all the studies you have been managing that have been completed that require CRO performance feedback.

Contracts missing KPIs for user ctravis

Task ID	Lead AI	CRO	Quality Index	Timeliness Index	Communication Index	Flexibility Index	Compliance Index	
CJTTEST	test2]<	ADME Bioanalyses	0	0	0	0		Edit
CJTTest2	2	AgroScience GmbH						Edit



Supplier Performance - KPIs

Contracts missing KPIs for user ctravis

Task ID	Lead AI	CRO	Quality Index	Timeliness Index	Communication Index	Flexibility Index	Compliance Index	
CJTTEST	test211	ADME Bioanalyses	3	0	3	0		Edit
CJTTest2	2	AgroScience GmbH						Edit

This is the task title

Where the score is Poor or Unacceptable please provide a brief explanation in the comments field provided.

Quality	The overall technical competence of the CRO to conduct and report studies including guideline compliance. 0-<not scored>
Timeliness	A measure of the CROs performance to provide protocols and reports to Syngenta on time 0-<not scored>
Communication	Ease and regularity of study information supplied by the CRO to Syngenta 0-<not scored>
Flexibility	Ability of the CRO to accommodate studies according to the required deadlines and ability to prioritise work at Syngenta's request 0-<not scored>
Comments	

Update

By clicking on the edit button you will see for that task 4 questions

TRAX - Performance Scores - Windows Internet Explorer

http://syngenta.dev.intra/Contracts/PerformanceScores.aspx

File Edit View Favorites Tools Help

Convert Select

mySyngen... Home: GL... TRAX: Ta... Quotations Invoices SRM: Ent... Plans/ware... TRAX: Ta... TRAX: Ta...

Page Tools

Contracts missing KPIs for user ctravis

Task ID	Lead At	CRO	Quality Index	Timeliness Index	Communication Index	Flexibility Index	Compliance Index	Edit
CJTTEST	test2]<	ADME Bicanalyses						

test8%

Where the score is Poor or Unacceptable please provide a brief explanation in the comments field provided.

The overall technical competence of the CRO to conduct and report studies including guideline compliance.

Quality: 3-Average Some minor quality issues

Timeliness: A measure of the CROs performance to provide protocols and reports to Syngenta on time

Communication: 0-<not scored>

Flexibility: 0-<not scored>

Comments: Although the study went well I had an number of issues with their Study Manager J SMITH

Update

100%

There are two options

1. Leave answer as 0 (if not appropriate time to answer)
2. Set answer to drop down of 1 -5.

All scales are the same 1 not good, 5 Excellent

If you do grade the performance indicator 1 or 2 please add a short comment in the comment field

By clicking on UPDATE this returns your answers live to the database.

KPI - PO Number:	
Where the score is Poor or Unacceptable please provide a brief explanation in the comments field provided.	
Quality	<p>The overall technical competence of the CRO to conduct and report studies including guideline compliance.</p> <p>3-Average Some minor quality issues</p>
Timeliness	<p>A measure of the CROs performance to provide protocols and reports to Syngenta on time</p> <p>0-<not scored></p>
Communication	<p>Ease and regularity of study information supplied by the CRO to Syngenta</p> <p>3-Average Information supplied when prompted</p>
Flexibility	<p>Ability of the CRO to accommodate studies according to the required deadlines and ability to prioritise work at Syngenta's request</p> <p>0-<not scored></p>
Comments	<p>Although the study went well I had an number of issues with their Study Manager J SMITH</p>
<input type="button" value="Update"/>	



Smartchoice and the outsourcing process

syngenta

What has or has not changed.

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What has changed



- **The acceptance criteria for tasks**
 - ✓ **Task must be set to Active – PM**
 - ✓ **Task location added – Function**
 - ✓ **Task contact added- Function**
 - ✓ **Task must have initial resources allocated to it – PM?**

Outsourcing

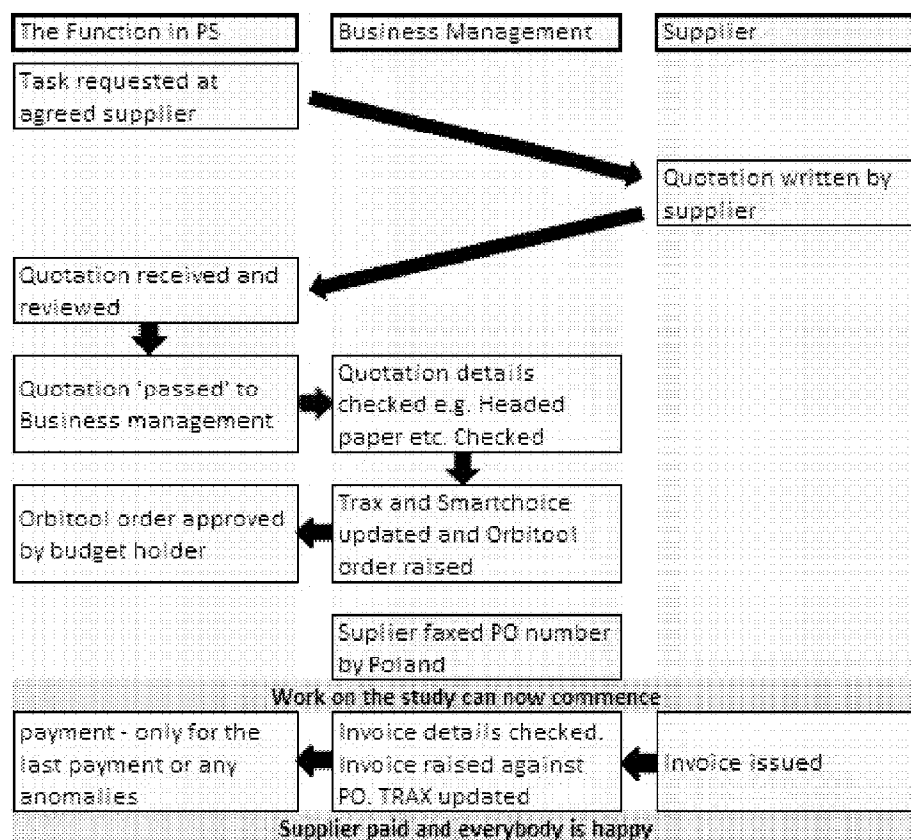
- ✓ **To process a quote or an invoice all the above must be correct or it will be returned to the SM.**

What has not changed



- **Actual Finish** and **Actual Start** dates
 - ✓ Need to be completed by the **function**
- Task status **Completed** and **Terminated**
 - ✓ Need to be changed by the **function**
- **Communication with the Project managers and project leads is key.**

The outsourcing process



- ✓ Secrecy agreement
- ✓ UTC
- ✓ Consultancy agreement
- ✓ Collaboration agreement
- ✓ Services agreement
- ✓ Budget approval
- ✓ Quote
- ✓ PO number
- ✓ Invoice

Budget Process

- Product safety “sits” within CPD – budget from CPD
- Other Syngenta “customers” pay for resources internal days/\$

Example:

- Total CPD budget for PS capped within CPD budget – example \$80m
- Total internal cost at Jhill / GSO – line budgets + Overhead
 - Example \$38m internal costs + \$12m overheads = Total \$50m
- Other functions pay fixed internal staff day costs e.g. M/S, R&T, Global supply, Traits/Seeds, other special budget lines
 - Example total internal costs “cross charged” to others = \$13.5m
- Net CPD Internal costs = \$50m - \$13.5m = \$36.5m
- Difference between Total CPD budget and Net CPD internal cost is PS Contract budget for CPD work = \$80m - \$36.5m = \$43.5m
- Other function contract \$ “pay as you go!”